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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/229,751	01/14/1999	CHARLES L. TURNBOUGH		5473

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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/229,751

Applicant(s)

TURNBOUGH, CHARLES L.

Examiner

T. D. Wessendorf

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*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 January 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9,11-14 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-9,14,16,17,19, 20, 25 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 11-13,18,21-24,26 and 27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the species, B. anthracis spore and peptide of claim 24 (TSQNVRT, Seq. No. 40 in Paper No. 23 is acknowledged. The traversal is on the ground(s) that the examination of other species would not present an undue burden for the examiner in view of the art. It is further argued that the means of identifying spore forming organisms by identification of the presence of spores using very small peptides was completely unknown. The method apparently being used at present is alleged to be a much more complex enzyme means. This is not found persuasive because: firstly, the restriction was made not because the examination would be an undue burden to the examiner, albeit this is so, but because the species are distinct differing in structures, not only for the peptide, but also for the different bacterial spores. Secondly, the claims are drawn to a composition and not to the argued method or means.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21 (species, B. cereus), 23(peptide, TYPXPXR) and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no

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allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 26.

Status of Claims

Claims 1-9, 11-14, 16-27 are pending in the instant application. **Claim 27** has been added in the present Amendment 1/8/03. [It is noted that the clean copy of the Present Amendment did not include claim 21. Claim 21 is still pending as per the Amendment of 1/29/02.]

Claims 23-25 and misnumbered claim 29 (now amended claim 26) have been added in the Amendment of 1/29/02.

Claims 1-9, 14, 16, 17, 19, 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim as stated by applicants in the Amendment of 8/4/00. Also, with this amendment, **claims 10 and 15** have been cancelled. **Claim 25** is withdrawn from consideration as being drawn to non-elected species. See below.

Claims 11-13, 18, 21-24, 26 and 27 are under consideration.

Specification

The disclosure is objected to because of the following informalities:

There is no Seq. ID. No. for the peptide sequences TYPXPXR recited at page 2, line 4; SPLX1X2H, line 36. Also, at line 33,

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ibid, the sequence TYPVPHR, Seq. ID. No.43 does not correspond to Seq. ID. 43 in the Sequence Listing. Furthermore, line 34, ibid, recites Seq. ID. 100. The Sequence Listing has only 80 sequences listed therein. Applicants are requested to check for other sequences recited in the specification that does not correspond with the Seq. ID. Nos. in the Seq. Listing and CRF and list sequences present in the specification but not in the Listing. Also, to appropriately assign Seq. ID. Nos. in the specification for those peptide sequences without sequence ID. Nos. A new Seq. Listing and CRF reflecting these corrections are required.

The specification has not been checked to the extent necessary to determine the presence of **all** possible minor errors (grammatical, typographical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 11-13, 18 and 21-24 and 26-27 are rejected under 35 U.S.C. 101 because the claimed composition is drawn to non-statutory subject matter.

The claimed composition drawn to a tagged peptide ligand and a sample containing the recited bacterial species is a non-statutory subject matter since it is drawn to a composition that occurs in nature i.e., an unpurified, isolated sample existing in its naturally occurring composition. The natural environment e.g., water or air pollutants which contains bacterial spores or organisms contain also other organic molecules such as peptides that binds to bacteria that forms a complex of bacteria-organic composition. The claims are clearly drawn to a composition of nature wherein the components have not been isolated or purified to identify the components present therein. Because the sample contains numerous components or constituents, it is possible that the peptide can be tagged by one of the natures' component present in the sample inasmuch as some of the naturally occurring residues in the peptide are known to be nature's fluorescence. See Ho (U.S. 5,895,922) specifically col. 3, lines

2-10.

Claim Rejections - 35 USC § 112, first paragraph

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13, 18, 21-24, 26-27 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A composition comprising of a peptide ligand having the different peptide sequences (e.g., TSQNVRT) identified by a phage method in the disclosure that binds to a bacterial spore with a carrier is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The specification, page 15, lines 12-14 discloses a purified peptide that is formulated with a pharmaceutically acceptable carrier such as buffered saline to produce a composition for administration to animals to elicit an immune response or to bind to the spore to cause alteration in the spore pathogenicity. However, the specification fails to teach how to make a composition comprising of a sample suspected to contain a bacterial spore. It is not apparent from the disclosure the determination of how a sample is suspected to contain a spore and a tagged peptide ligand and the means by

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which a tagged peptide binds to said spore. The disclosure is unclear with respect to the exact components present in a sample to make a composition comprising said sample and a tagged peptide sequence. It cannot be discerned from the specification teaching just how crude the sample is to enable binding to a tagged peptide ligand and detection of such binding especially for a sample simply suspected of containing a bacterial spore. See Grow (U.S. 6,040,191) particularly at col. 5, lines 2 [The invention appears to reside in a modified biopanning method that identifies a peptide ligand from a library that binds specifically to the disclosed bacterial spores].

The specification further fails to teach how to make and use a composition comprising of a solid support wherein the solid support takes the different forms of a tape, sponge or filter. It is not clear from the general statements contain in the specification, page 15,lines 5-6, as to how the support takes the different forms of a sponge or tape or filter. It is further not apparent in the disclosure as to the kind of material that assumes said different form or the manner by which the material acts in the capacity of the different forms. Likewise, the specification fails to teach how to make and use a peptide ligand with any 5-12 mers peptide sequences. The specific peptide obtained from the specification does not provide an enabling disclosure for the 5-12 of undefined sequences containing every conceivable amino acid residues,

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modified or unmodified, as well as the binding ability of the peptide to bind to a spore in a sample.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13, 18, 21-24 and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 21 and 27 are unclear as to the definite components of a composition. A composition which contains a sample of unknown components does not particularly point out what is included or excluded from the claimed sample composition. Further, it is not clear how binding of the tagged peptide ligand of undefined structure as the claimed 5-12 mers to a spore in a sample is determined, in the absence of positive recitation in the specification.

B. Claim 22 is indefinite as to whether the tagged peptide ligand is bound to a solid support as part of a composition or

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will need to be bound to a solid support. "Being" bound is vague as to whether the tagged peptide is able to bind (or not).

C. Claims 18 and 23 are unclear as to the peptide ligand in a liquid medium. If the tagged peptide is contained in a sample, won't the peptide be in a liquid medium? If this is not so, then it is not clear as to the liquid medium the peptide ligand is contained therein.

D. Claim 12 is unclear as to how the solid support forms a filter or what is being filtered, especially in the absence of positive support in the specification. Is a filter different from the claimed sponge?

E. Claim 13 recitation of a solid support as a tape or sponge is unclear as to what constitutes a tape or sponge, within the claimed context, especially in the absence of positive support in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by applicants' disclosure of known prior art. [This rejection is based on *B. subtilis*. The search has been extended since there is no prior art for the elected peptide sequence, TSQNVT, SEQ. ID. 40].

The disclosure, page 7, lines 20-30, discloses "a search of the Swiss-Prot data base of characterized peptides for proteins containing the sequence...seven proteins with this sequence were identified...two are *B. subtilis* proteins. The first....is SpSC...which contains the NHFLP... (i.e., MVQKRNHFLP...) SpSC appears to be involved in the synthesis of polysaccharides on the surface of the spore. It is probable that this protein uses its amino terminus to attach to a receptor on the spore surface. The instantly claimed peptide ligands may bind to the same site...." Accordingly, the broad claimed composition comprising of 5-12 mer peptide of undefined sequence is fully met by the prior art specific peptide contained in the protein, as admitted by applicants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13, 18, 21-24, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ezzell et al (Jrnl. of Clinical Microbiology) in view of D'Mello (Virology).

Ezzell discloses a composition comprising a peptide ligand i.e., a monoclonal antibody that binds to Bacillus spores and a sample suspected of containing said Bacillus spores. See particularly, page 223, abstract; page 226, col. 1 up to page 228, col. 1. Ezzell does not disclose a peptide ligand with 5-12 mer of B. antracis. However, D'Mello discloses at e.g., page 320, cols. 1 and 2; page 322, cols. 1 and 2 a composition comprising of a peptide ligand of 7-mer that identifies the critical region for binding of monoclonal antibody using phage display library. It would have been obvious to one having ordinary skill in the art at the time the invention was made to obtain or identify in the monoclonal antibody of Ezzell's composition the peptide region that binds to spore since D'Mello discloses that shorter fragment or region of a protein is the critical region by which a monoclonal antibody binds to its receptor or spore. One skilled in the art would be motivated to use a shorter length peptide, not only for easy synthesis but because it is well known in the art that binding of a peptide

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resides only on a portion of a protein. This shorter length peptide has been known to provide for a lead compound useful for diagnosis or therapy of pathogens.

Claim 11 is obvious in view of D'Mello's disclosure of a polymeric support, page 320, cols. 1 and 2.

Claim 23 (elected peptide sequence of SEQ. ID. 40 that binds to B. antracis spore) and claim 24 are free of prior art.

No claims are allowed.

REASSIGNMENT OF LOCATION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit **1639**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. W
T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
January 12, 2003